REMARKS/ARGUMENTS

Status of the claims

Claims 1-3, 5, and 9-12 are pending. Claims 1 and 2 are amended. Support for the amendments can be found on page 12, line 9-14 and page 11, lines 20-25. No new matter is added.

Applicants appreciatively acknowledge the withdrawal of the rejection under the first paragraph of 35 USC § 112 for enablement.

Priority document

Please find enclosed a certified translation of the priority document, Japanese Appl. No. 2002-196290.

Rejection under 35 USC § 103

The Examiner has rejected the claims as allegedly obvious over Wasmoen in view of Motokawa. In response to applicant arguments, the Examiner states that the claims encompass both Type I and Type II N proteins. According to the Examiner, Motokawa provides motivation to use type I FIPV as a vaccine strain because a person of ordinary skill would know that less infectious strain would be a better choice for a vaccine and would have greater access to the most common FIPV.

The Examiner has not shown that one of skill would reasonably expect a vaccine as recited in the present claims to be effective for prophylactic treatment or conferring cellular immunity in a cat

Applicants respectfully maintain that one of skill would not have a reasonable expectation of success in making an effective FIPV vaccine based on an N protein from Type I FIPV. Solely in an effort to expedite prosecution, the claims are amended to exclude N proteins from Type II FIPV.

As explained in the response submitted July 31, 2008, Wasmoen teaches a vaccine comprising a recombinant Type II FIPV N-protein in a racoon poxvirus host. Thus,

Wasmoen discloses introduction of recombinant N protein with different antigenicity than the previously described ineffective N-protein based FIPV vaccines (*see* Wasmoen col. 1, lines 64-67).

The FIPV vaccine described by Wasmoen is not widely acknowledged in later reports in the field, while the difficulty with designing N-protein based FIPV vaccines continued to be described. Wasmoen *et al.* published their results in a corresponding article, *Adv Exp Med Biol* 380:221-28 (1995).

For example, **Ex. A** (German *et al.* (2004) *J. Feline Med. Surgery* 6:119-124), published six years after Wasmoen issued, indicates that attempts to design vaccines against FCoV (FIPV) have been unsuccessful. Page 119, col. 1 states:

> Development of vaccines has been largely unsuccessful, with traditional approaches sometimes serving to exacerbate the disease…. The identification of FCoV epitopes responsible for neutralisation and enhancement is still under investigation.

The report continues to note that unsuccessful approaches include those based on use of the N protein as a target.

The response submitted July 31, 2008 explains that one of skill would be dissuaded from using the N protein as an epitope for an FIPV vaccine. The N protein is not expressed on the surface of the virus. Moreover, use of a Type I epitope presents technical challenges, because Type I FIPV proliferates slowly and is less pathogenic than Type II FIPV. Neither Wasmoen nor Motokawa suggest use of a Type I FIPV N protein for use as a vaccine.

Given the difficulties facing a skilled artisan in using a Type I FIPV based vaccine, one of skill would not have a reasonable expectation of success in making a FIPV vaccine based on the N protein from a Type I FIPV.

The Examiner states that one of skill would be motivated to use a less pathogenic virus strain for a vaccine. The claimed vaccine, however, is a subunit vaccine, and does not rely on a disabled or attenuated virus where a less pathogenic strain might be preferred. For the purposes of a subunit vaccine, one of skill would generally not use a protein from a less pathogenic virus to promote an immune response in a host.

The claimed invention meets a long felt but unsolved need where others had failed

MPEP § 2145 discloses that secondary considerations include long felt but unsolved needs, failure of others, and evidence of unexpected results. The claimed invention presents all of these.

Ex. A, described above, indicates that there was a need in the field for an effective FIPV vaccine, and that others had failed in meeting this need. **Ex. A** also focuses on the need for a FIPV vaccine targeting the Type I serotype.

Ex. B (Horzinek (2004) *J. Feline Med. Surgery* 6:49-51) is among the reports that comment on presentations made at the Second International FcoV/ FIP Symposium in Glasgow. **Ex. B** is an editorial from Dr. Marian Horzinek, a well-respected feline coronavirus expert. The commentary addresses coronaviruses broadly, but notes on page 50 that little progress has been made in designing vaccines to feline coronaviruses (such as FIPV). Page 50, col. 1 states

> Feline medicine has not profited from these advances in coronavirus biology and pathogenesis – the diagnostics and vaccine scene has been stagnant for years, irrespective of many efforts.

Ex. B thus provides further evidence of the long-felt need and failure of others in making an effective FIPV vaccine.

Dr. Horzinek continues, however, and notes the surprising and hopeful results reported in the present application. The inventors published these results in Hohdatsu *et al.* (2003) *Veterinary Microbiol.* 97: 31-44 (provided as **Ex. C**). Page 50 states

> In a study published last December, cats had been immunized with recombinant baculovirus-expressed N protein of a Type I FIPV; they produced homologous antibodies, but of course, no virus-neutralizing ones. A DTH skin response to N [protein] was observed in the vaccinated cats, so cellular immunity had kicked in, and when they were challenged with heterologous FIPV, **survival amounted to 75%, which is very high for this type of experiment.** *Emphasis added.*

This passage from a highly respected FIPV researcher indicates that the present invention meets a long unsolved need where others have failed. Moreover, Dr. Horzinek indicates that the present invention is unexpectedly effective, with a survival rate of 75%. The results obtained from the presently claimed vaccines demonstrate the unexpected effectiveness of a Type I FIPV based vaccine.

Note that **Ex. A** was accepted in August 2003, prior to the publication of **Ex. C**, and thus does not comment on the results.

One of skill would not have a reasonable expectation of success in designing a FIPV vaccine using a Type I N protein. The presently claimed vaccines represent a solution to the long felt need of an effective FIPV vaccine where others had failed. As explained above, the surprising efficacy of the vaccine is acknowledged by at least one expert in the field. In view of the foregoing, Applicants respectfully request withdrawal of the rejections under 35 USC § 103.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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